

California Medical Device Recall Information



Recall Name

Lumenis Limited Recalls VersaCut Morcellator Due to Potential for Air Embolisms

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|--------------|--|------------------------------------|---|
| 01/02/13 | A medical device used to break up and remove dissected tissue during surgical procedures. | Lumenis Limited Yokneam, Israel | Inaccurate device labeling leading to incorrect hook up of aspirating tubing. Incorrect assembly could cause the introduction of air embolisms resulting in serious adverse health consequences including death. |
| Recall Class | Product Identification | Distribution | Affected Dates |
| I | VersaCut Morcellators Model Numbers: • 0637-245-01 (starter kit) • 0636-470-01 (control box) | CA, nationwide | All units manufactured since May 1998 |

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm340943.htm